THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In re: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	MDL NO. 1871
THIS DOCUMENT RELATES TO: Case No.: 2:10-cv-01637-CMR	:	CIVIL ACTION NO.: 2:10-cv-01637-CMR
COUNTY OF SANTA CLARA and THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Acting Santa Clara County Counsel Lori E. Pegg,	:	
Plaintiffs,	:	
-vs.-	:	
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE L.L.C.,	:	
Defendant.	:	

GLAXOSMITHKLINE LLC'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT (LIMITING SCOPE OF COUNTY'S CLAIMS)

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I. INTRODUCTION

The Final Judgment in the action brought by the People of California in San Diego Superior Court against GlaxoSmithKline LLC ("GSK") carved out this action from the People's release of GSK, but the Final Judgment also stated: "This exclusion applies to and in favor of only persons or entities resident in the County."[1] Ignoring this limitation, the County argues in opposition to GSK's motion for partial summary judgment that the Court may award restitution in favor of persons outside the County, notably to payors elsewhere who paid for prescriptions written in the County.

The County makes two major points. First, the County states that the motion is premature because discovery is not complete and the Court has no need to decide the motion now. The issues presented by GSK's motion do not require further discovery to resolve. Rather, the Court should resolve the issues now because a resolution will define the boundaries of remaining discovery, thereby ensuring that the parties' discovery is focused on the County's physicians, residents, and payors.

Second, the County, using words that are not found in the Final Judgment, argues that "the plaintiff" may recover restitution "from transactions involving [County] residents" who were "connected" to GSK's alleged false advertising. Opposition Brief ("Opp.") at 6. The Final Judgment does not provide an exclusion from the release for transactions "involving" County residents or for residents who were "connected" to alleged false advertising, as the County suggests. *Id.* Rather, the exclusion in the Final Judgment allowing this action to proceed applies only to residents of the County who were "exposed" to alleged false advertising and any award of restitution must be "in favor of only persons or entities resident in the County." Ex. A, ¶ 11.E.

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[1] Ex. A., Final Judgment, ¶ 11.E.

GSK respectfully requests that the Court confirm the plain meaning of the Final Judgment and grant GSK's motion.

II. ARGUMENT

The language of the Final Judgment governs the scope of the County's case, which the County does not dispute.[2] The Final Judgment settled all claims brought by the Attorney General of California on behalf of the People of California based on alleged violations of the False Advertising Law ("FAL") and the Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 and 17500 *et seq.*, in connection with Avandia, except for those limited claims set forth in Paragraph 11. The only provision of Paragraph 11 that applies to the County is sub-section 11.E, which states:

> 11. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:
>
> ***
>
> E. Any claims that have been brought by the Santa Clara County Counsel's Office, as of the date of entry of this Judgment, for violations of California Business and Professions Code section 17500 concerning all Covered Conduct as defined in this Judgment, *to which persons resident in the County of Santa Clara were exposed. This exclusion applies to and in favor of only persons or entities resident in the County.*[3]

Notwithstanding this language, the County argues that "Plaintiff may recover restitution of any monies wrongfully acquired by GSK from transactions involving those residents," and, in similar language, contends that "Plaintiff may recover restitution for all

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[2] Opp. at 3 ("Plaintiff does not dispute, and has in fact filed an amended complaint admitting, that it is bound by the terms of the California AG's Final Judgment.").

[3] Final Judgment, ¶ 11.E (emphasis added).

transactions involving Santa Clara residents – either as payers or receivers of Avandia prescriptions – connected to GSK's false advertising to which Santa Clara residents were exposed." Opp. at 6. This jumbled mischaracterization amounts to a complete re-writing of the Final Judgment, which does not use the words "involving" or "transactions" or "connected to."

The critical words of the exclusion in paragraph 11.E are simple: "persons residents in the County"; "exposed"; "applies to" and "in favor of." These words mean what they say, and they have a practical consequence. It is residents of the County who must be exposed to the alleged false advertising, and any award of restitution must apply to and be in favor of a County resident. Thus, the only persons entitled to an award of restitution would be County residents who paid for Avandia. As noted in GSK's opening brief, the County's re-writing of the exclusion would allow a court to award restitution to Humana, Inc. if it had paid for a prescription for a person resident in the County, even though Humana is based in Louisville, Kentucky.

By the Final Judgment, the People of California (*i.e.*, the State) have resolved their claims under the FAL against GSK with respect to restitution to patients and payors *outside* the County. The County's interpretation of the Final Judgment would subject GSK to the risk of having to pay restitution to payors outside the County and to civil penalties or other orders for conduct occurring outside the County -- claims that GSK resolved. This would be plainly inconsistent with the release in paragraph 10 of the Final Judgment, and with other paragraphs of the Final Judgment pursuant to which GSK paid $7.3 million to the Attorney General, which she can use for restitution,[4] and agreed to certain "Compliance Provisions."[5]

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[4] Final Judgment ¶ 9.

[5] *Id.* at ¶¶ 7-8.

The County attempts to distance itself from the words of the exclusion in the Final Judgment by an extended discussion of what the County believes to be the basis for restitution under California law under the FAL. Opp. at 5-8. GSK disagrees with the County's view on California law, and the Court need not reach these issues: the Final Judgment controls. Because the County raised these issues, GSK will reply briefly.

The County argues that a court may order what is really disgorgement of monies from GSK with no or minimal connection between the alleged false advertising and any loss suffered by anyone who paid for Avandia. Opp. at 6-7. For example, the County argues that restitution may be awarded for "all monies wrongfully acquired" "even if only some Santa Clara residents were exposed to GSK's false and deceptive conduct." Opp. at 7. By this language, the County apparently suggests that if 10% of Santa Clara physicians were exposed to alleged false advertising, a court could award restitution to 100% of Santa Clara patients who took Avandia and to out-of-County payors who covered the cost of Avandia prescriptions in the County. This is clearly wrong.

In the FAL, the word "restitution" is not used but a court may make an order as "necessary to restore to any person in interest" monies which were "acquired by means" of false marketing. Cal. Bus. & Prof. Code § 17535. The California Supreme Court defines restitution in the context of the FAL and UCL as the "return [of] money obtained through an unfair business practice to those persons in interest from whom the property was taken, that is, to persons who had an ownership interest in the property . . . ." *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1144-45 (Cal. 2003). Restitution centers on a victim's loss and returning what was wrongfully taken from them:

> The object of restitution is to restore the status quo by returning to the plaintiff funds in which he or she has an ownership interest.

> Consistent with that objective, restitutionary awards encompass quantifiable sums one person owes to another . . . . Such awards represent money that once had been in the possession of the person to whom it [is] to be restored.

Feitelberg v. Credit Suisse First Boston, LLC, 134 Cal. App. 4th 997, 1012-13 (Cal. Ct. App. 2005) (quotations and citations omitted). In contrast, "disgorgement" compels a defendant "to surrender all money obtained through an unfair business practice even though not all is to be restored to the persons from whom it was obtained . . . ." *Id.* at 1145.

Although "restitution" is permitted in a FAL action, "disgorgement" is not. *See Korea Supply Co.*, 29 Cal. 4th at 1144-45, 1152 ("We hold that nonrestitutionary disgorgement of profits is not an available remedy in an individual action under the UCL."); *State of California v. Altus Finance*, 36 Cal. 4th 1284, 1304 n.7 (Cal. 2005) (extending this reasoning to public action suits brought by the Attorney General, and by implication, County Counsel); *Feitelberg*, 134 Cal. App. 4th at 1020 (observing that "[a]lthough *Korea Supply* involved an individual private plaintiff, its rationale has broader application," and concluding that "[b]ecause the UCL is the specific substantive law from which plaintiff's claims arise, it controls the remedies that may be obtained . . . .").[6]

Thus, should the Court, in its discretion, award restitution, it may order a return of monies in which County residents have a direct and personal ownership interest. Persons resident in the County whose prescriptions were paid for in whole or part by third parties have no

[6] GSK is not, as the County argues, ignoring this Court's observation that restitution under the FAL has the purpose of deterring violations of the statute by depriving a defendant of some of its wrongful gains. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig*, 2011 U.S. Dist. LEXIS 124458, at *11-12 (E.D. Pa. Oct. 26, 2011). Even though an award of "restitution may have a collateral law enforcement effect, [by] punishing the wrongdoer against whom restitution is sought," *Altus Finance*, 36 Cal. 4th at 1305, its primary purpose centers on restoration of a victim's losses, *Korea Supply Co.*, 29 Cal. 4th at 1149. As California Courts have observed, the equitable grant of power given to courts by § 17535 to "prevent" the use of practices which violate the FAL does not, as the County suggests, authorize orders mandating the surrender of all gains. *See Feitelberg*, 134 Cal. App. 4th 997, 1016-19 (Cal. Ct. App. 2005); *Korea Supply Co.*, 29 Cal. 4th at 1147-49.

ownership interest in monies spent by those third parties. *See Korea Supply Co.*, 29 Cal. at 1149 (concluding that an "ownership interest" was lacking where funds sought were neither originally possessed by nor taken directly from the plaintiff). Therefore, the County may not pursue all revenue or profits, including sums paid for Avandia by non-resident third parties, merely because the underlying transactions are "connected" to the County. This is not part of "restitution" under the FAL.[7]

The County also devotes much attention to its beliefs about how it needs to prove its FAL claims in order to prevail. *See* Opp. at 7-8. Whether or not the County needs to show exposure by individualized proof or some other method is irrelevant to the question of the scope of the claims remaining in this case after the Final Judgment. Thus, the County's invocation of the *In Re Tobacco II Cases* and its strained attempts to reframe a matter of contract interpretation as one relating to proof and causation is a mere distraction.[8] The Final Judgment makes clear that the County may proceed only on behalf of County residents who were exposed to alleged false marketing. How the County proves exposure, causation, or any other element of its claim is not at issue here.

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[7] The County's reliance on class action cases to suggest that it may pursue recovery of funds spent by out-of-state payors because those payors might, under different circumstances, bring their own claims under California law is not only misplaced, but is also revealing about the County's true intentions in this case. *See* Opp. at 5 n.15 & 16. The County does not and cannot represent out-of-County persons or entities under the terms of the Final Judgment, nor can it bring an action under the FAL on behalf of anyone besides the People of California. Nonetheless, it aims to incorporate claims those non-residents might bring on their own behalf into the confined scope of its own FAL action. This attempt highlights the County's disregard for the limits imposed by the Final Judgment as well as California law.

[8] To the extent *In re Tobacco II Cases*, 46 Cal. 4th 298 (Cal. 2009) has any bearing on the issues before this Court, it reinforces GSK's position with respect to the scope of the County's claims, particularly concerning restitution. The portion cited by the County, Opp. at 8, reaffirms that an award of restitution may only be made to a person having an ownership interest in funds wrongfully taken from them. *See id. at* 323 (observing that "the purchasers in question may have purchased contaminated eggs--therefore, the *'money or property' of* the entire class of *purchasers* 'may have been acquired by means' of an unfair practice . . . *thus entitling them to restitution for their loss*." (emphasis added)). Here, the class of purchasers is limited to residents of the County and no one more.

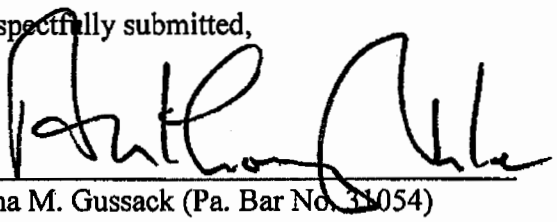
Finally, the County argues at length that the location of exposure need not be within the County itself. Although GSK believes this is implied by the terms of the Final Judgment, GSK would not object in the rare circumstances where the County was able to show that one of its residents was exposed to alleged false marketing outside the County. The central limitation – that any award of restitution and all other remaining claims only be made to and brought on behalf of County residents who were exposed to alleged false marketing – still applies and represents the central limitation on the scope of the County's remaining action.

III. CONCLUSION

For the foregoing reasons, and those set forth in GSK's Motion, GSK respectfully asks this Court to enter partial summary judgment in GSK's favor, dismissing plaintiff's claims, whether for civil penalties or restitution, to the extent they are brought on behalf of persons and entities not resident in the County of Santa Clara itself or are not based on alleged false advertising to which a County resident was exposed.

Date: June 25, 2013

Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Gabriel J. Vidoni, hereby certify that on this 25th day of June 2013, I caused the foregoing Reply Memorandum of Law in Support of GlaxoSmithKline LLC's Motion for Partial Summary Judgment to be served by first class mail and electronic mail upon the following:

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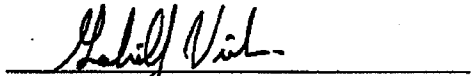

Gabriel J. Vidoni

EXHIBIT

A

(of memorandum of law)

FILED
Clerk of the Superior Court
NOV 15 2012
By: L. SAN NICOLAS, Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN DIEGO

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff,

v.

GLAXOSMITHKLINE LLC,

Defendant.

Case No. 37-2012-00085491-CU-MC-CTL

FINAL JUDGMENT

Plaintiff, the People of the State of California ("Plaintiff" of the "People"), having filed its Complaint and appearing through its attorney, Kamala D. Harris, Attorney General of the State of California, by Judith Fiorentini and Jinsook Ohta, Deputy Attorneys General, and GlaxoSmithKline LLC ("GlaxoSmithKline," "GSK" or "Defendant") by its attorneys Pepper Hamilton LLP, by Nina M. Gussack, Esq., Barry H. Boise, Esq., and Harry P. Weitzel, Esq., having stipulated as follows to the entry of this Final Judgment ("Judgment") by the Court without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind as follows:

That this Judgment may be signed by any judge of the San Diego Superior Court; and

That Plaintiff has filed its Complaint in this matter pursuant to California Business and Professions Code sections 17200 et seq. and 17500 et seq.; and, GlaxoSmithKline denies the allegations of the Complaint and denies any alleged violations; and

That this Judgment is made without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind; and that GlaxoSmithKline does not admit any violation of law or any wrongdoing and that no part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault or wrongdoing by GlaxoSmithKline; and

The Court having considered the pleadings and the Stipulation for Entry of Final Judgment ("Stipulation") executed by the Plaintiff and GlaxoSmithKline filed herewith, and good cause appearing,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

I. PARTIES AND JURISDICTION

1. The People of the State of California is the plaintiff in this case.

2. GlaxoSmithKline is the Defendant in this case. GlaxoSmithKline, at all relevant times, has transacted business in the State of California, including, but not limited to, San Diego County.

3. The Court has jurisdiction over the subject matter of this action, jurisdiction over the parties to this action, and venue is proper in this Court.

4. This Judgment is entered into pursuant to and subject to California Business and Professions Code sections 17200 et seq. and 17500 et seq.

5. The terms of this Judgment shall be governed by the laws of the State of California.

II. DEFINITIONS

6. The following definitions shall be used in construing this Judgment:

A. "Applicable Clinical Trials" shall mean those clinical trials required by the Food and Drug Administration ("FDA") Amendments Act of 2007 (Public Law No. 110-85).

B. "Attorneys General" shall mean the Attorneys General of the Multistate Working Group.

C. "Avandia" shall mean and include all formulations of rosiglitazone, a diabetes drug in the class of thiazolidinediones ("TZDs"), that GSK sells or sold under the brand name Avandia, Avandamet, and Avandaryl.

D. "Covered Conduct" shall mean Promotional practices and dissemination of information by GlaxoSmithKline LLC regarding Avandia in the United States.

E. "Defendant" shall mean GlaxoSmithKline LLC.

F. "Effective Date" shall mean the date on which a copy of this Judgment is approved by and becomes a Judgment of the Court.

G. "GlaxoSmithKline LLC" or "GSK" shall mean GlaxoSmithKline LLC, all of its officers, directors, employees, subsidiaries, divisions, predecessors, successors, assignees, and transferees.

H. "GSK Diabetes Product" shall mean any pharmaceutical product approved by the Food and Drug Administration for the improvement of glycemic control for patients with Type 2 diabetes and that GSK Promotes, or for which it directs the Promotion.

I. "Health Care Economic Information" shall mean data and other information relating to the inputs and outcomes of health care therapies and services, including, but not limited to, the price, cost-effectiveness, and quality of life implications of any GSK Diabetes Product.

J. "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

K. "Multistate Executive Committee" shall mean the Attorneys General and their staff representing Arizona, Florida, Illinois, Maryland, Oregon, Pennsylvania, Tennessee, and Texas.

L. "Parties" shall mean the State of California and Defendant.

M. "Promotional," "Promoting" or "Promote" shall mean representations about a GSK Diabetes Product intended to influence sales of that product, including attempts to influence prescribing practices and utilization of a GSK Diabetes Product.

N. "Promotional Materials" shall mean any item used to Promote any GSK Diabetes Product.

III. COMPLIANCE PROVISIONS

Promotional Activities

7. In accordance with sections 17203 and 17535 of the California Business and Professions Code:

A. Defendant shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive about any GSK Diabetes Product.

B. Defendant shall not represent that any GSK Diabetes Product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

C. The following subsections shall be effective for a period of the greater of either: eight years from the Effective Date of this Judgment, or five years from approval by the FDA of a GSK Diabetes Product other than Avandia.

1. Defendant shall only Promote GSK Diabetes Products for uses permitted under the FDA-approved labeling or the Federal Food, Drug, and Cosmetic Act ("FDCA").

2. Defendant shall not represent in a promotional context that an investigational new GSK Diabetes Product is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information in non-promotional settings concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict

promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

3. Defendant shall not make in a promotional context a representation or suggestion, not approved or permitted for use in the labeling or under the FDCA, that a GSK Diabetes Product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence, or substantial clinical experience (as described in paragraphs (e)(4)(ii)(*b*) and (*c*) of 21 C.F.R. § 202.1), whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

4. Defendant shall not Promote any GSK Diabetes Product by use of Promotional Materials that:

a. contain a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience;

b. contain favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contain literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience;

c. contain a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or

minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated;

d. contain favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated;

e. use erroneously a statistical finding of "no significant difference" to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference;

f. present required information relating to side effects or contraindications by means of a general term for a group in place of disclosing each specific side effect and contraindication unless the use of such general term conforms to the provisions of paragraph (e)(3)(iii) of 21 C.F.R. § 202.1;

g. present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; and/or

h. use statistics on numbers of patients or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

5. When presenting information about a clinical study regarding GSK Diabetes Products in any Promotional Materials, Defendant shall not do any of the following for information that may be material to a health care provider prescribing decision:

a. present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

b. use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; and/or

c. use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

Clinical Research

8. In accordance with sections 17203 and 17535 of the California Business and Professions Code:

A. The following subsections shall be effective for eight years from the Effective Date of this Judgment.

1. Defendant shall report research in an accurate, objective and balanced manner as follows and as required by applicable law: to the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act of 2007 (Public Law No. 110-85), Defendant shall register GSK-sponsored Applicable Clinical Trials beginning after the Effective Date with the applicable registry and submit results of GSK-sponsored Applicable Clinical Trials completed after the Effective Date to the registry and results data bank as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act.

2. When submitting a manuscript on the results of a clinical study regarding any GSK Diabetes Product for publication, Defendant shall:

a. Adhere to the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications, including authorship criteria, unless the applicable journal or congress to which the publication is submitted has more stringent requirements, in which case the journal or congress criteria for authorship will be followed; and

b. Acknowledge Defendant's role as a funding source of the study which is the subject of the manuscript.

3. For any GSK Diabetes Product, Defendant shall also post on GSK's clinical study registry any observational studies or meta-analyses conducted by GSK that are designed to inform the effective, safe, and/or appropriate use of any GSK Diabetes Product.

4. Summaries of the results of GSK-sponsored interventional clinical trials of medicinal products that are approved for the improvement of glycemic control in Type 2 diabetics will be posted on a publicly available registry within eight months of the study primary completion date. Such summaries will be posted on either the National Institute of Health's ("NIH") register at www.clinicaltrials.gov or on GSK's clinical study register with information fields consistent with the NIH register.

IV. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

9. Within thirty days of the Effective Date of this Judgment, Defendant shall pay ninety million dollars to be divided and paid by Defendant directly to each Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee, except for California's share which shall be paid by Defendant to the California Attorney General's Office within forty-five days of the Effective Date of this Judgment.[1] The payment allocated to the California Attorney General's Office shall be used by the Attorney General for attorneys' fees and other costs of investigation and litigation, restitution, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education

[1] The State of California's share is $7,347,855.68.

or litigation or local consumer aid or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of the Attorney General. The Attorney General may, in her sole discretion, direct a portion of the payment to one or more California counties. The Parties acknowledge that the payment described herein is not a fine or penalty, or payment in lieu thereof.

V. RELEASE

10. By execution of this Judgment, the State of California releases and forever discharges Defendant and all of its past and present officers, directors, shareholders, employees, parents, subsidiaries, divisions, predecessors, successors, assignees, and transferees (collectively, the "Released Parties"), from the following: all civil claims, causes of action, damages, restitution, fines, costs, attorneys' fees, remedies and/or penalties that were or could have been asserted against the Released Parties by the Attorney General under California Business and Professions Code sections 17200 and 17500 or any amendments thereto, or by common law claims other than claims asserted or that could be asserted under Section V.11 concerning unfair, deceptive, or fraudulent trade practices resulting from the Covered Conduct, up to and including the Effective Date of this Judgment (collectively, the "Released Claims").

11. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

A. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of California;

B. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of California, under any statute, regulation, or rule not expressly covered by the release in Section V.10 including, but not limited to, any and all of the following claims:

1. State or federal antitrust violations;

2. Reporting practices, including "best price," "average wholesale price" or "wholesale acquisition cost";

3. Medicaid violations, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to California's Medicaid program;

4. State false claims violations; and

5. Claims to enforce the terms and conditions of this Judgment.

C. Actions of state program payors of the State of California arising from the Covered Conduct, except for the release of civil penalties under the State of California's above-cited state consumer protection law.

D. Any claims individual consumers have or may have under the State of California's consumer protection laws against any person or entity, including Released Parties.

E. Any claims that have been brought by the Santa Clara County Counsel's Office, as of the date of entry of this Judgment, for violations of California Business and Professions Code section 17500 concerning all Covered Conduct as defined in this Judgment, to which persons resident in the County of Santa Clara were exposed. This exclusion applies to and in favor of only persons or entities resident in the County.

VI. CONFLICTS

12. If, subsequent to the Effective Date of this Judgment, the federal government or any state, or any federal or state agency, enacts or promulgates legislation or regulations with respect to matters governed by this Judgment that creates a conflict with any provision of the Judgment and Defendant intends to comply with the newly enacted legislation or regulation, Defendant shall notify the Attorneys General (or the Attorney General of the affected State) of the same. If the Attorney General agrees, the Attorney General shall consent to a modification of such provision of the Judgment to the extent necessary to eliminate such conflict. If the Attorney General disagrees and the Parties are not able to resolve the disagreement, Defendant shall seek a modification from an appropriate court of any provision of this Judgment that presents a conflict with any such federal or state law or regulation. Changes in federal or state laws or regulations, with respect to the matters governed by this Judgment, shall not be deemed to create a conflict

with a provision of this Judgment unless Defendant cannot reasonably comply with both such law or regulation and the applicable provision of this Judgment.

VII. DISPUTE RESOLUTION

13. For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the signatory Attorneys General have a reason to believe that Defendant has violated a provision of this Judgment subsequent to the Effective Date, then such Attorney General shall notify Defendant in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Defendant thirty days to respond to the notification.

14. Upon receipt of written notice from any of the Attorneys General, Defendant shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Defendant believes it is in compliance with the Judgment or a detailed explanation of how the alleged violation occurred and statement explaining how and when Defendant intends to remedy the alleged violation.

15. Except as set forth in Sections VII.17 and 18 below, the Attorney General may not take any action during the thirty-day response period. Nothing shall prevent the Attorney General from agreeing in writing to provide Defendant with additional time beyond the thirty days to respond to the notice.

16. The Attorney General may not take any action during which a modification request is pending before a court pursuant to Section VI.12, except as provided for in Sections VII.17 and 18 below.

17. Nothing in this Judgment shall be interpreted to limit the State's Civil Investigative Demand, Administrative Subpoena, or investigative subpoena authority.

18. The Attorney General may assert any claim that Defendant has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing Defendant an opportunity to respond to the notification and to remedy the alleged violation within the thirty-day response period as described above, or within any other period as agreed to by GSK and the Attorney General; provided,

however, that the Attorney General may take any action if the Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

VIII. COMPLIANCE WITH ALL LAWS

19. Except as expressly provided in this Judgment, nothing in this Judgment shall be construed as:

A. Relieving Defendant of its obligation to comply with all applicable state laws, regulations, or rules, or granting permission to engage in any acts or practices prohibited by any law, regulation, or rule; or

B. Limiting or expanding in any way any right any state represented by the Multistate Working Group may otherwise have to enforce applicable state law or obtain information, documents, or testimony from Defendant pursuant to any applicable state law, regulation, or rule, or any right Defendant may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

IX. GENERAL PROVISIONS

20. This Court retains jurisdiction over this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

21. This Judgment relates solely to the Covered Conduct.

22. This Judgment (or any portion thereof) shall in no way be construed to prohibit Defendant from making representations with respect to any GSK Diabetes Product that are permitted under Federal law or labeling for the drug under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry, or permitted or required under any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application approved by FDA, so long as the representation, taken in its entirety, is not false, misleading or deceptive.

23. Nothing in this Judgment shall require Defendant to:

A. take any action that is prohibited by the FDCA, 21 U.S.C. § 301 et seq., or any regulation promulgated thereunder, or by FDA; or

B. fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA;

C. or shall preclude Defendant from providing Health Care Economic Information to a formulary committee or similar entity or its members in the course of the committee or entity carrying out its responsibilities for the selection of drugs for managed care or other similar organization pursuant to the standards of the Food and Drug Administration Modernization Act, Section 114, if the information directly relates to an approved indication of a GSK Diabetes Product, and if based on competent and reliable scientific evidence.

24. Nothing in this Judgment is intended to modify the Judgment, effective June 23, 2011, among the State of California and GlaxoSmithKline LLC and SB Pharmco Puerto Rico, Inc.

25. Nothing in this Judgment is intended to modify the Settlement Agreement, effective June 27, 2012, between the State of California and GlaxoSmithKline LLC.

26. Nothing will prevent the Attorney General from agreeing in writing to provide Defendant with additional time to perform any act required by the Judgment. The Attorney General shall not unreasonably withhold her consent to the request for additional time.

27. All notices under this Judgment shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For GlaxoSmithKline LLC:

Barry H. Boise
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103

For the State of California:

California Attorney General's Office
Attn: Judith Fiorentini, Deputy Attorney General
110 West A Street, Suite 1100
San Diego, CA 92101

28. The Clerk is ordered to enter this Judgment forthwith.

Dated: NOV 15 2012

WILLIAM S. DATO

JUDGE OF THE SUPERIOR COURT